AMIS, Inc. DBAGIRITIONALS. HFS-450
William's Natural Foods
P.O. Box 394
Yarmouth, ME 04096
(207)846-9508

March 7, 1997.

0045 '97 SEP 19 P1:31

Food and Drug Administration Office of Special Nutritional (HFS-450) 200 'C' Street, S.W., Washington D.C. 20204

Dear Sir,

I would like to inform you that I am making the following Nutritional Support Statements which I have substantiation that the statements are truthful and not misleading according to 403(r)(6) on the product 'SOLUFIBER'. The product was first marketed in October 3, 1996 but only started to have the following statements beginning March 1, 1997.

Taking Solufiber could have a significant effect on your blood sugar and fat levels. Solufiber contains Chinese herbs Dong Quai and Astragulus that increase the tone of the blood and liver. Together with garlic, ginger, onion and other ingredients, Solufiber provides a balanced formula to help keep your fat and blood sugar levels where you want them.\*\*

\*\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'

Thank you.

Sincerely,

William Wong, President.

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975-0162

LET 557



660 Madison Avenue, 18th Floor • New York, NY 10021 • 212-754-6491 • FAX: 212-888-5598

March 7, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington DC 20204
Tel: (202) 205-5372

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To whom this may concern:

Please let this letter act as official notification to the Office of Special Nutritionals (HFS-450), Center for Food Safety and Applied Nutrition and the Food and Drug Administration that we (Dental Research Laboratories) will be marketing a dietary supplement product ("DentalPlus"), beginning on March 10, 1997.

In accordance with the Dietary Supplement Health and Education Act of 1994, we (Dental Research Laboratories) have emphasized only those claims about the product ("DentalPlus"), which pertain to structural and functional concerns (section 403(r)(6)(A) of the act). The following statement that "the special combination of ingredients in 'DentalPlus' works to give you stronger, healthier teeth and gums" has been made and printed on the product's package. Attached is a list of the product's ("DentalPlus") ingredients and formulation structure about which the above statement is being made.

In addition to this claim, please be aware that we (Dental Research Laboratories) have included, in accordance with the requirements of the DSHEA, the statutorily required disclaimer that "these statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease" (section 403 (r)(6)(c)).

Please contact me if I may be of any further assistance in this matter.

Cordially,

James J. Nicholas

encl: ingredient/formulation list

copies

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## NUTRITIONAL FACTS

The special combination of ingredients in DentalPlus works to give you stronger, healthier teeth and gums. DentalPlus protects your mouth in 3 important ways:

Strengthens Oral Immune System <sup>†</sup>				Strengthens Gums†				Strengthens Teeth And Bone <sup>†</sup>			
Amount per Zinc Vitamin A Vitamin B <sub>1</sub> Vitamin B <sub>2</sub> Vitamin B <sub>3</sub> Vitamin B <sub>6</sub> Vitamin B <sub>12</sub> Riotin	15 5000 45 4.5 5.1 30 3	mg IU IU mg	100 100 150 300 300 150 150	Amount per Vitamin C Bioflavonoids Rutin Hesperidin Iron Folic Acid Ovalbumin containing 8 Essential	240 75 25 25	mg mg mg mg	400 ** 100 g 100	Amount per Calcium Phosphorus Magnesium Vitamin D Vitamin K Manganese Iodine Copper	tablet 200 r 35 r 100 r 200 i 25 r 100 r 1 r 100 r 1 r	ng ng ng ng	20 4 25 50 67 50
Selenium Pantothenic Acid Chromium	10	mcg mcg	100	Amino Acids  * Percentage of the U.S. Recommended Daily Allowance for adults and children ages 4 and older.  ** Recommended Daily Allowance not established.							

Directions: Serving size one tablet. Adults take one (1) tablet daily as a dietary supplement, preferably with a meal.

Distributed by **Dental Research Laboratories**, **Inc.**, New York, NY 10014 † These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

Code 2386F-Rev. 0-9/96

Patent Pending